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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,966

10/06/2005

Shmuel Ben Muvhar

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12/24/2008

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EXAMINER

LANG, AMY T

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

12/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,966	Applicant(s) BEN MUVHAR, SHMUEL	
	Examiner AMY T. LANG	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/25/2008 has been entered.

Oath/Declaration

3. Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath, declaration or application data sheet does not acknowledge the filing of any foreign application or US application. A new oath, declaration or application data sheet is required in the body of which the present application should be identified by application number and filing date. Specifically, the oath or declaration does not acknowledge US 09/534,968, PCT/IL01/00284, PCT/IL/02/00805, PCT/IL03/00303, IL 151162, IL 152366, IL 153753. This objection is maintained until a replacement is filed.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **Claims 1-11 and 23** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites wherein the rod is springy. However, the instant specification does not specifically disclose a springy rod attached to a balloon.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-11 and 23** are rejected under 35 U.S.C. 102(b) as being anticipated by Klein (US 5,863,284).

With regard to **claims 1, 4, 9-11, and 23**, Klein discloses a balloon catheter comprising a balloon body (32) attached to rods (18) that conforms to a surface of the balloon (Figures 1A, 3, and 4; column 13, line 66 through column 14, lines 9). The balloon comprises an elastomeric material, specifically polyurethane, while the rods (18) comprise a radioactive material so that the two members are made of different materials (column 10, lines 15-28; column 13, lines 11-30). Klein further teaches wherein the

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balloon expands the rods to apply contact force to a vessel lumen (column 10, lines 1-7). Additionally, Klein teaches the rods are directly attached to the balloon (column 9, lines 55-60). The rods are further disclosed as flexible and additionally are able to bend outward, which overlaps the instantly claimed springy (column 13, lines 23-25).

With regard to **claims 2**, as shown in Figures 2 and 3, the balloon is elongate and the rods are provided along a long dimension of the balloon.

With regard to **claim 3**, shaft (33) clearly overlaps the instantly claimed tether (Figure 2).

With regard to **claim 5**, as shown in Figure 4, the rods are attached to each other at their proximal and distal ends.

With regard to **claims 6 and 7**, in one embodiment the rods are directly attached to the balloon so that the rods modify the geometry of the balloon when not inflated (column 9, lines 55-60). Furthermore, the rods are then configured to compact said balloon in a resting condition.

With regard to **claim 8**, since the rods apply radially outward pressure when inflated, it is the examiner's position that the rods are configured to also apply radially outward pressure when in a resting condition (column 14, lines 5-9).

With regard to **claim 11**, the rods are configured to substantially surround the balloon when the balloon is collapsed (Figures 2-4).

8. **Claims 12-16, 21, and 22** are rejected under 35 U.S.C. 102(b) as being anticipated by Kavteladze et al. (US 5,863,411).

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With regard to **claim 12, 21, and 22**, Kavteladze et al. (hereinafter Kavteladze) discloses a vascular implant comprising a flexible band (16) having a diameter suitable for implantation in a blood vessel (column 5, lines 43-50) and a plurality of elongate axial elements (12) mounted on said band. As shown in Figure 3, the flexible band (16) comprises an inner opening which clearly overlaps the instantly claimed flow passage. When implanted within a blood vessel, this flow path would inherently restrict the flow of blood due to the small opening and members 12 impeding blood flow.

With regard to **claim 13**, the flexible band (16) is disclosed as thin (Figure 4).

With regard to **claim 14**, the flexible band has a thickness suitable for restricting blood flow (Figure 3).

With regard to **claim 14**, as shown in Figure 3, the flexible band (16) has a length substantially smaller than the length of the elements (12).

With regard to **claim 16**, the flexible band is elastic (column 5, lines 30-33, 46).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. **Claims 12, 21, and 22** are rejected under 35 U.S.C. 102(e) as being anticipated by Morris (US 2004/0158280 A1).

As shown in Figure 1 and 6B, Morris discloses a vascular implant comprising a flexible band (32) having a flow passage ([0069]). When the implant is placed within a vessel, the perforations in the band material would restrict blood flowing through the

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flow passage (Figure 1). Morris teaches wherein a plurality of elongate elements (21, 23, 25, 27) are mounted on the outside of the band ([0081]; Figure 6B).

Claim Rejections – 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. **Claims 17, 19, 20, and 24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruiz (US 6,120,534).

With regard to **claims 17 and 19**, Ruiz discloses a blood flow reducing implant comprising a body (10) defining a flow channel (20) having a cross section which is progressively restricted along an axial direction (Figure 2A), in which the smallest diameter of a cross-section is sized for passage of a guidewire (30; Figure 4B). Although Ruiz teaches the implant is used to impede blood flow, Ruiz does not specifically teach the implant as sized to block substantially all blood-flow.

However, Ruiz teaches that the constricted flow channel can be constricted to create a large flow impedance (column 5, lines 4-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the implant of Ruiz to be utilized in such a way and create a large blockage of blood flow. It would have been obvious for the large blockage to block substantially all blood flow. And blockage of substantially all blood-flow there through, over 95% (column 4, lines 60-67).

With regard to **claim 20**, said smallest diameter (13) is restricted by an elastic sheath (Figure 2A, 16).

Response to Arguments

14. Applicant's arguments filed 09/25/2008 have been fully considered but they are not persuasive.

Specifically, applicant argues (A) that Klein does not teach rods directly attached to the balloon.

With respect to argument (A), as stated above, Klein specifically discloses the rods as directly contacting the balloon and therefore directly attached to the balloon (column 9, lines 55-60). Therefore, the rods conform to the surface of the balloon by moving with the balloon and changing shape with the balloon.

Specifically, applicant argues (B) that Kavteladze does not disclose axial elements mounted on an outer surface of the band.

With respect to argument (B), as shown in Figure 3 of Kavteladze, the axial elements (11) are mounted on an outer surface of the band (16). By extending through the band's aperture, the axial elements are mounted within and on the band. "Mounted" refers to putting into position or to place on. Since the axial elements of Kavteladze are put into place within the band's aperture, they are mounted on the band. Additionally, the aperture forms an outer surface on which the bands extend through.

Specifically, applicant argues (C) that the implant of Kavteladze does not restrict the flow of blood since it functions as a vessel occlusion device that stops blood flow completely.

With respect to argument (C), it is the examiner's position that Kavteladze merely states wherein the implant "may completely obturate a vessel lumen" (column 5, lines 443-46). Therefore, Kavteladze does not disclose wherein the implant is intended to always completely stop blood flow, instead Kavteladze teaches in one embodiment where blood flow is completely stopped. Therefore, Kavteladze also teaches embodiments where blood flow is not completely stopped.

Specifically, applicant argues (D) that the device of Ruiz does not block substantially all blood flow nor does it restrict blood flow along an axial direction.

With respect to argument (D), as discussed above, it is the examiner's position that it would have been obvious at the time of the invention to utilize the Ruiz implant to block substantially all blood flow. Since the implant is able to create a large impedance,

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it would have been obvious for it reduce 95% of blood flow through the implant.

Additionally, this blood flow is reduced along an axial direction. Blood flowing along the longitudinal axis, an axial direction, is restricted due to the occluding device of Ruiz.

Specifically, applicant argues (E) that PET is a hard and stiff material and therefore Morris does not overlap the instantly claimed implant.

With respect to argument (E), PET varies from semi-rigid to rigid. Therefore, an embodiment where the PET is only semi-rigid infers that the material comprises some flexibility. Therefore, the PET overlaps a flexible band so that Morris discloses an implant as claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

12/16/2008

/Amy T Lang/

Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731